REMARKS

STATUS OF THE CLAIMS

Applicants respectfully request entry of the amendment to claim 1 as it places the claims in condition for allowance and/or in better position for appeal. Claims 1, 10, 25-32 are pending in the present application and under examination. Claims 7, 9, 13, 15, 17, 19, 21, 23-24, and 33 are withdrawn and claims 2-6, 8, 11-12, 14, 16, 18, 20, and 22 are canceled.

TELEPHONIC INTERVIEW

The applicants thank the Examiner for the Telephonic interview on October 10, 2005, wherein the finality of the Office Action issued October 4, 2005 was confirmed by the Examiner.

REJECTION OF CLAIMS UNDER 35 U.S.C § 112, FIRST PARAGRAPH (NEW MATTER)

Claims 1 and those dependent therefrom have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The applicants respectfully assert that the specification provides support for the presently pending claim 1. The specification clearly indicates on page 2, lines 7-9, that the invention includes polypeptides that have 70% sequence identity to the proteins fragments, as is presently claimed. Furthermore, the invention also clearly includes the purified form of such polypeptides. The specification on page 2, lines 18-22, clearly states that, "The proteins of the invention can, of course be prepared by various means (e.g., recombinant expression, ***purification from cell culture,*** chemical synthesis, etc.) ... " (emphasis added). One of skill in the art would readily recognize that purification from cell culture would result in a purified polypeptide as is presently claimed. Thus, the specification clearly conveys to one of skill in the art that the inventors had possession of "a ***purified*** polypeptide comprising a contiguous amino acid sequence with at least ***70% sequence***

identity to the sequence of SEQ ID NO:133," as is presently claimed and that such polypeptides were proteins according to the present invention.

The specification also provides support for the recitation "at least one antigenic determinant that elicits an immune response against Neisserial bacteria ..." The specification on page 3, lines 20-27, indicates that the invention "also provides the use of nucleic acid, ***protein***, or antibody ***according to the invention*** [e.g., such as the claimed purified polypeptides] in the manufacture of: ... (iii) ***a reagent which can raise antibodies against Neisserial bacteria***." One of skill in the art would recognize that a polypeptide that may be used as a reagent which can raise antibodies against Neisserial bacteria would have "at least one antigenic determinant that elicits an immune response against Neisserial bacteria," as is presently claimed. Therefore the present claim 1 does not include new matter.

Therefore the applicants respectfully request that the Examiner withdraw the rejection of Claim 1 and the claims that depend therefrom based upon 35 U.S.C. § 112, first paragraph (new matter).

REJECTION OF CLAIMS UNDER 35 U.S.C § 112, FIRST PARAGRAPH (Enablement)

Claims 1, 10 and 25-32 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly not reasonably providing enablement for a polypeptide that has a length of 20, 35, 50, or 100 amino acids or less and comprises a contiguous amino acid sequence with "at least 70% sequence identity to SEQ ID NO: 1331," wherein the polypeptide comprises at least one antigenic determinant "that elicits an immune response against Neisserial bacteria," as claimed.

The Examiner has asserted that the claims are not enabled due to an alleged lack of specific guidance, lack of enabling disclosure, art demonstrated functional unpredictability, breadth of the claims, and the quantity of experimentation.

The applicants respectfully disagree. The application does provide specific guidance as to preferred fragments as described on page 37, lines 8-29 and pages 64-71 which disclose preferred fragments of 114-1 (SEQ ID NO:1331). Further, as noted on page 18-19 of the response filed June 21, 2005, the specification also provides general guidance to those of skill in the art. By "lack of enabling disclosure," the applicants assume that the Examiner is referring to working examples; however, working examples are not required to enable an invention.

Regarding unpredictability in the art, the Examiner appears to be asserting that in order for an invention to be enabled, one of skill in the art must be able to predict with one hundred percent accuracy whether any given polypeptide meeting the sequence identity would provide the claimed function. However, by analogy to monoclonal antibodies, this is not required for enablement. It is well established that claims to monoclonal antibodies directed to a particular protein are enabled where the application discloses the sequence of the protein. Clearly, with just the protein sequence, one of skill in the art could not predict the sequences of any of the monoclonal antibodies directed to that sequence. However, such claims are enabled because it is a routine procedure to immunize an animal such as a rabbit with the protein, generate monoclonal hybridoma from the rabbit and screen them for monoclonal antibodies which are directed to the protein. With the present claims, the procedure is very similar and even more routine. One of skill in the art need only synthesize a set of peptide fragments of the claimed sequence identity and length limitations, the selection of which may be guided by the preferred fragments listed in the specification. Such synthesis was so routine as of the priority date of the present application that one of skill in the art could order such purified polypeptides from a company. Then the person of ordinary skill in the art need merely immunize an animal such as a rabbit and draw and screen blood for polyclonal antibodies which recognize the original protein 114-1 (i.e., a Neisserial bacterial protein). Drawing and screening polyclonal antibodies in the blood is an even simpler task than generating hybridoma and screening monoclonal antibodies produced from them. This clearly addresses the Examiner's concerns regarding any unpredictability and the amount of experimentation required. Thus, it would not require undue experimentation to make and use the claimed invention, which means that the claimed invention is enabled.

Therefore the applicants respectfully request that the Examiner withdraw the rejection of Claims 1, 10 and 25-32 based upon 35 U.S.C. § 112, first paragraph, enablement.

REJECTION OF CLAIMS UNDER 35 U.S.C § 112, SECOND PARAGRAPH

Claims 1, 10 and 25-32 have been rejected under 35 U.S.C. § 112, second paragraph, as claim 1 allegedly lacks antecedent basis for "the sequence of SEQ ID NO: 1331," and claims 10 and 25-32 depend therefrom.

Applicants respectfully disagree with the Examiner's grounds for rejection. However, in order to facilitate prosecution in this case applicants have amended the pending claim 1, without prejudice or disclaimer, to add "amino acid" to claim 1 per the Examiner's suggestion.

Therefore the applicants respectfully request that the Examiner withdraw the rejection of Claims 1, 10 and 25-32 based upon 35 U.S.C. § 112, second paragraph.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

Please direct all further written communications regarding this application to:

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In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 223002100200. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: December 5, 2005

Respectfully submitted,

By _____

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